

Healthcare IT Investments

What's behind the Gartner Forecast?



Service Industry Association Executive Summit
Las Vegas, NV - March 5-7, 2006

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BioBrief: Elliot Sloane

"Dual citizenship" in Clinical Engineering
and Information Systems and Technology!

30+ Years of CE and IT/IS Expertise

- **Faculty, Department of Decision and Information Technologies, Villanova University, since 2000**
 - Teaching, research and publishing in databases, decision support, healthcare technology assessment and management, Telecommunications, and health informatics.
 - Senior Member, IEEE
 - Board of Directors, IEEE Engineering in Medicine and Biology Society
 - Past President, ACCE
 - Board of Directors, ACCE Healthcare Technology Foundation
 - Advisor to WHO/PAHO in Healthcare Technology Management since 1985
- **Vice President, MEDIQ/PRN - 10 Years, COO & CTO**
 - Medical device & drug distribution, service, rental, and manufacturing
 - Former SIA Director
- **Vice President, ECRI - 15 years, CIO & CTO**
 - Medical technology research, testing, and education; medical device nomenclature; standards directories; product evaluations; forensic/accident investigations

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Healthcare IT Investments Overview

- Characteristics of today's market?
- Trends for the future market?
- What is driving the changes?
- What is facilitating the changes?
- Critical success factors for servicers and service partnerships:

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Healthcare IT Investments Topic 1

- Characteristics of today's market?

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Healthcare is the largest single market sector in the US...

- Between 1 in every 4 or 5 dollars spent in the US goes to healthcare!
 - That may not include vitamins, homeopathic supplements, exercise, etc.
- Costs growing at double-digit rates
 - How long will it take to double at 10%?
 - Rule of 7's...

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Estimated waste in healthcare is huge...

- Estimates run up to 30%! (e.g., Intel)
 - Duplicated and wrong services;
 - Wasted drugs;
 - Errors even cause repeated hospitalization:
 - Government statistic: In 2004, 425,000 patients had to be admitted to hospitals for post-surgical complications!

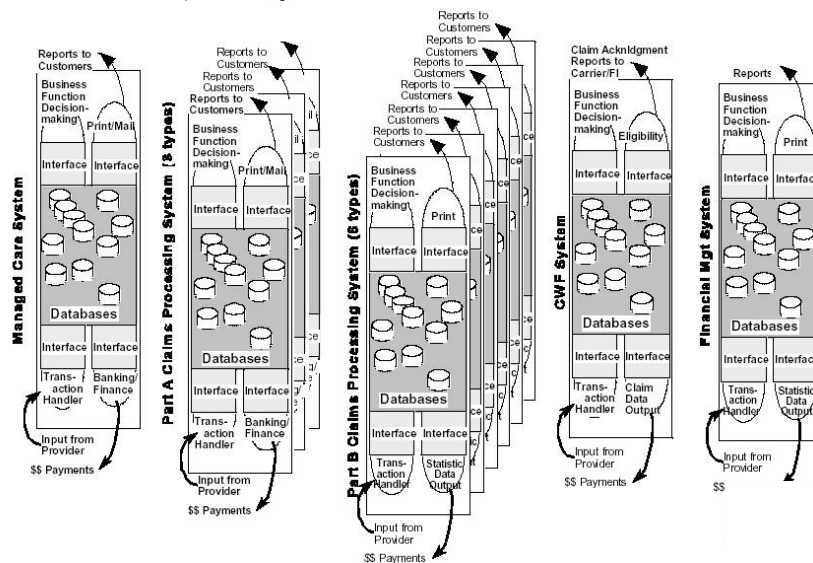
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Medical errors cause huge number of patient deaths and injuries...

- 1999 estimate by the Institute of Medicine was up to 98,000 US patients were killed or seriously injured by medical errors ANNUALLY
 - Roughly equal to 1 Boeing 747 crash every other day!
- Personal observation: the above numbers are low (home care, no care, etc. cause more than most experts see.)

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Government medical reimbursement was "siloed;" Pays over 60% of US medical costs!



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Healthcare IT Investments Topic 2

- Characteristics of today's market?
- **Trends for the future market?**

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1st: HIPAA is not what most of the public thinks!

- It never was about privacy protection...
- It **IS** about a wholesale shift of the medical marketplace to EDI by brute market force: The government refused to pay for medical care unless providers shifted to a uniform EDI system by 2005.
 - Privacy was a byproduct.
- WHY?

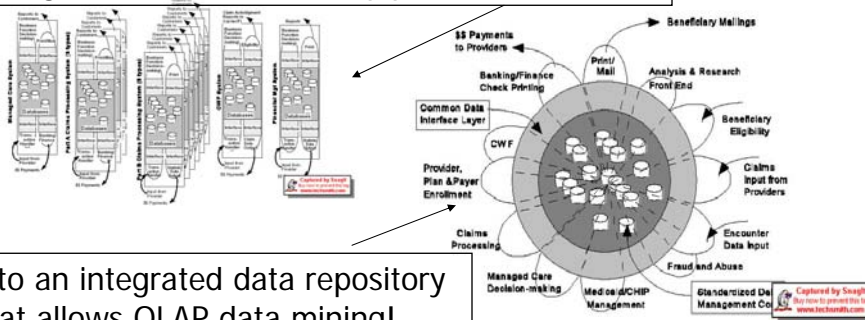
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Food for thought:

HCFA had a 5-year plan!

(<http://www.hcfa.gov/publications/5plan/irm5ypln.htm>)

To go from the old “stove pipe” architecture...



...to an integrated data repository that allows OLAP data mining! (FY 2001-2005)

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Underneath HIPAA's support

- A decision by the Federal government to use EDI for data-mining:
 - Verbage like “find and eliminate under-performers”
 - CMS has test cases under way with hospitals like Partners to pay “bonuses” for higher quality/safety medical care.
 - ***Guess the strategy for “underperformers!”***

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2nd: We have a VERY rapidly aging population...

Older Population by Age: 1900 to 2050 (Numbers)

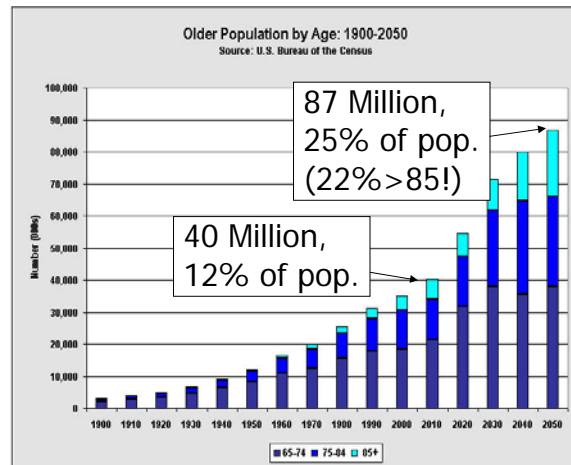


Table compiled by the U.S. Administration on Aging based on data from the U.S. Census Bureau.

In 2005, the Social Security Administration extended the US life expectancy tables to 119 years!

Dr. E's Quick Quiz:

What is a Medical Device?

- According to the FDA, it is **ANY** product that affects the **diagnostic or therapeutic care** of a patient.
- Also, according to the FDA, if an IEEE 802.11g Wi-Fi access appliance is used to transfer life-critical data or alarms, **the Wi-Fi access point is treated as a medical device!**

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3rd: IT-Medical device convergence is creating NEW devices!

- But, according to the FDA, the manufacturer is the hospital!
- No FDA regulatory incursions into hospitals yet, but based on prior experience with Single Use Medical Devices, that is NOT impossible.

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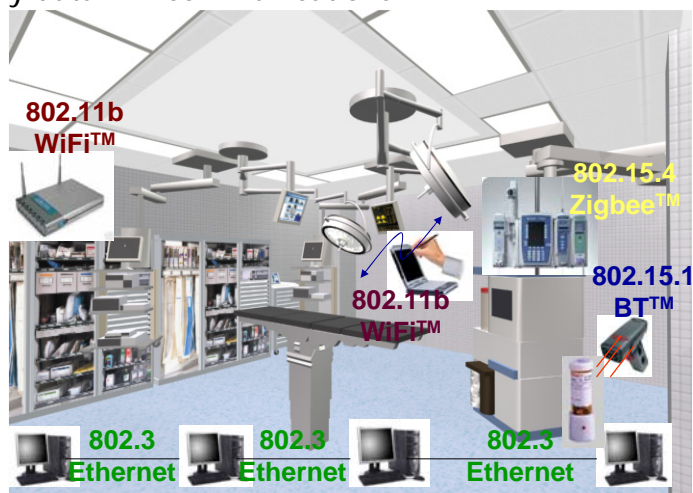
EXAMPLE of Hospital-created "medical device:" Using universal wireless interfaces to replace hard wires and proprietary data link communications:

Untethered access to information

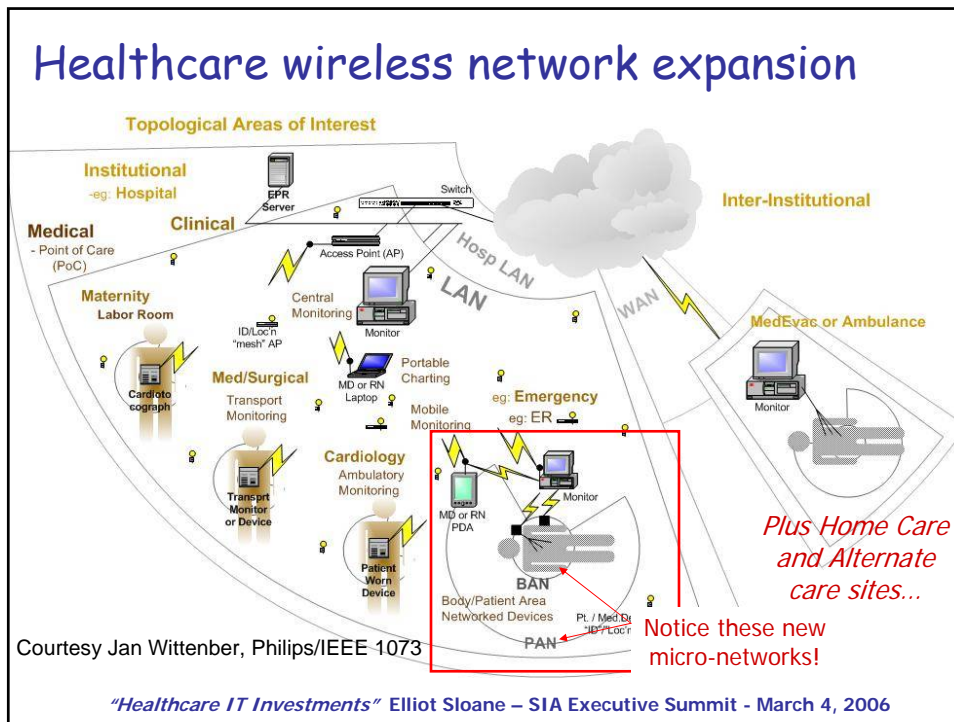
Mobility

Interoperability

Reduced cost and complexity



Courtesy of NIST



- ## Potential FCC services utilized in and around a hospital...
- ISM (Industrial, Scientific, Medical)
 - WMTS (Wireless Medical Telemetry Service)
 - PLMRS (Private Land Mobile Radio Service)
 - Public Safety
 - Bio-medical Telemetry
 - Industrial/Business
 - Private Land Mobile Paging
 - Radiolocation
 - Paging
 - MURS (Multi-Use Radio Service)
 - FRS (Family Radio Service)
 - GMRS (General Mobile Radio Service)
 - MICS (Medical Implant Communications Service)
 - Part 15
 - Medical Telemetry
 - RFID
 - Spread Spectrum
 - U-NII (Unlicensed National Information Infrastructure)
 - UWB (Ultra WideBand)
 - Medical Imaging
 - Cellular Radio Service
 - SMRS (Specialized Mobile Radio)
 - AWS (3G) - Advanced Wireless Services Spectrum
 - PCS (Personal Communications Service)
 - *Amateur Radio*
 - Private Operational Fixed Microwave
- (Courtesy Rick Hampton / Partners, Boston)
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Healthcare IT Investments Topic 3

- Characteristics of today's market?
- Trends for the future market?
- **What is driving the changes?**

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Prime Driver #1: TECHNOLOGY

- **Examples:**
 - **Essentially free communication via the Internet.**
 - **Cheap, ubiquitous, wireless links.**
 - *Cheap microprocessors allow continuous device reconfiguration and improvements.*



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Change Driver #2

- Medical device-related standards are finally receiving support.
 - From companies like GE, Siemens, Philips, AND Intel, Cisco, Microsoft, Sun, etc.

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Current IEEE 1073 RF Wireless Projects

- 20103 – *Application profile - Clinical context management (CCoM)*
- 30400 – *Inter-LAN (vLAN, IP, medical session, QoS, security, UDP, TCP, multicast discovery, addressing characters)*
- 30500 – *RF wireless – Framework & Overview*
- 30503 – *RF wireless – Local area network (wLAN)*
- 30505 – *RF wireless – Wide area (mobile phone) network (wWAN)*

AND, these will rapidly become global ISO standards, too!

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Proposed IEEE 1073 Projects

- 20401 – Network directory service (find & bind)
- 20402 – QoS [transport indépendant]
- 20403 – Location services (patient, equipment, ...)
- 20404 – ID Services (RFID, patient, supply chain mgmt, ...)
- 20500 – Security F&O (PnP Security profile)
- 305xx – wPAN (Bluetooth / 802.15.1 based)
- 305xx – Mesh Networks (802.15.5?)
- 305xx – 802.15.3a (UWB)
- 305xx – 802.15.4 (Zigbee) addressed as it emerges in healthcare

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And the Biggest Driver behind "Door #3" is?



American Health Information Community Workgroups



Welcome to the American Health Information Community (the Community) Workgroups Web site.

- <http://www.hhs.gov/healthit/ahic/workgroups.html>

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HIPAA + AHIC = TIPPING POINT!

- The source of the majority of payments to healthcare providers, CMS, will NOT pay for non-HIPAA, non-AHIC compliant services [e.g., EDI-driven system that automatically feeds the Electronic Health Record (EHR) for ALL chronic care patients.]
- *By the way, Private Insurers simply mimic CMS, to justify immediate payment cuts.*

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Healthcare IT Investments Topic 4

- Characteristics of today's market?
- Trends for the future market?
- What is driving the changes?
- **What is facilitating the changes?**

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Executive Order 13335 -Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator



Federal Register

Friday,
April 30, 2004

Part VII

The President

Executive Order 13335—Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator

- Dr. David Brailer appointed as National Coordinator for Health Information Technology in May 2004.
- ONCHIT will develop, maintain, and direct the implementation of a strategic plan to guide the **nationwide implementation of interoperable health information technology in both the public and private health care sectors** that will reduce medical errors, improve quality, and produce greater value for health care expenditures.
- ONCHIT will report on development of Strategic Plan within 90 days of appointment.

Aside from CMS payment “incentives,” who is paying for all of this new software?

- Federal law changes are in the works:
 - Private physicians may get a \$250,000 tax write-off for new computer systems...
 - Anti-trust laws in medicine (“The Stark Amendments” from the '70's) are being revised to allow large computer gifts to physicians and hospitals without triggering bribery and antitrust arrests.
- BTW, the taxpayers pay for all of this, but won't be visible.

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What else is breaking up this Chicken & Egg Problem?

HIMSS, RSNA, and ACC's Integrating the Healthcare Enterprise (IHE), and ACCE's IHE Patient Care Devices domain...

- *Planning Committee drives use case-based requirements*
- *Technical Committee develops interoperability profiles*
- *Coordinated closely with other IHE domains, incl. ITI*
- *Providers and vendors coordinate to their mutual benefit*
- *Profiles integrating RF wireless- a key area of interest!*

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Reality Check: Medical Device Interoperability Status Today?

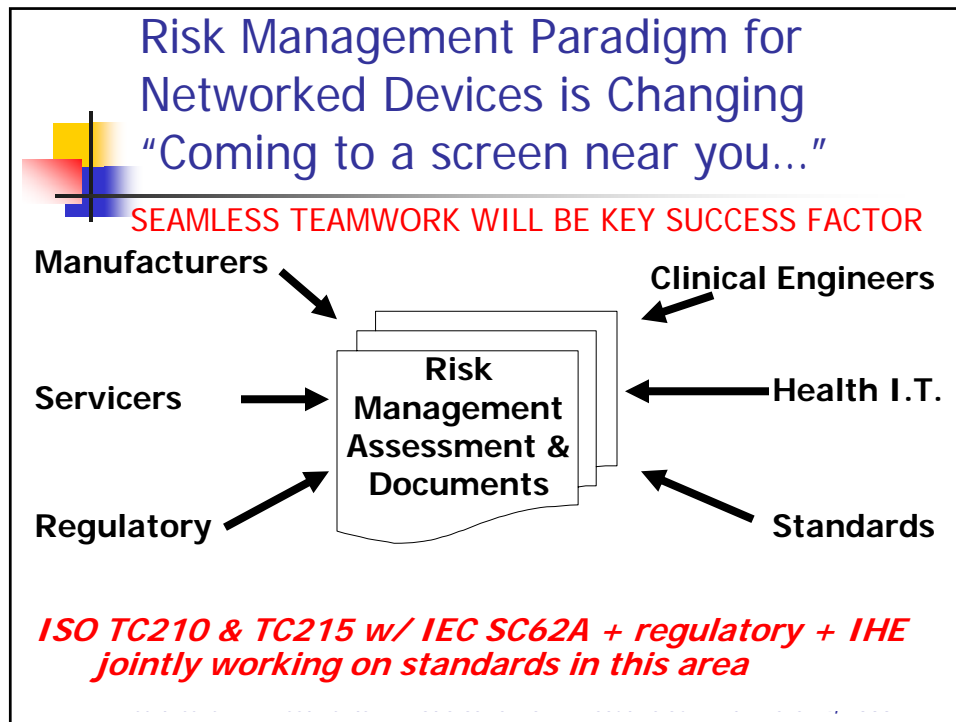
**State of open standards-based medical
device connectivity?**

Nonexistent!

*Proprietary / semi-standard Interfaces + Partnerships =
Security & lower risk for vendors*

**This is business issue, not a lack of technology
or standards, though. Intel, Cisco,
Microsoft and others have no vested
interest in the status quo!**

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Simplify – Integrate – Automate
SIA

- **Simplify** – standards for medical devices allow imbedding at the chip level;
- **Integrate** – Deploy IHE, creating interoperability between all medical specialties;
- **Automate** – use standards-driven and IHE-enabled information to automatically generate bills, manage the supply chain, populate the Electronic Health Records, and forecast demand and health trends.

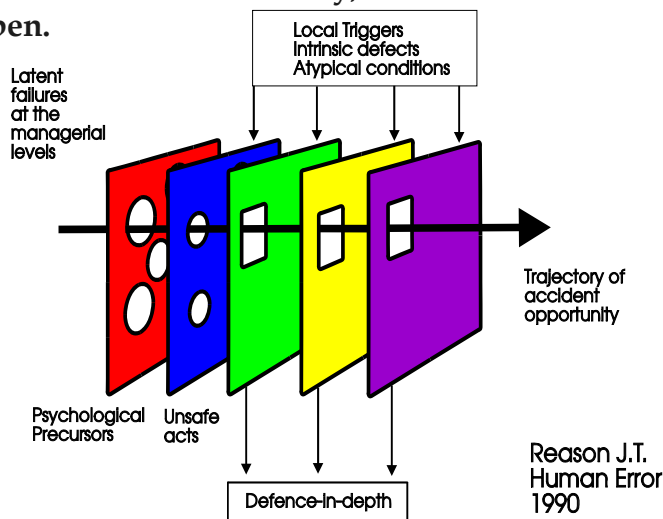
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Medical Device Service and Medical Software Support Opportunities:

- Open, integrated platforms eliminate proprietary solutions. This enables multi-vendor, multi-modality service and support for all parties.
- SWOT – **Opportunity**: Partnering with ISO's becomes feasible AND desirable.
- SWOT – **Threat**: Barriers to entry from offshoring will not be inconsequential.

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Closing Thought about **RISK**: Service Partnerships must really consider, and take ownership of the "Swiss Cheese Model of Accident Causality," or **serious accidents WILL** happen.






FDA regulation of medical device service is unlikely, but NOT impossible!

- Almost happened 10 years ago
 - Original FDA cGMP Proposal in 1994
 - Commentary & Meetings - Action delayed for ISO's
 - Second FDA Proposal - Dec. 1997
 - Notification of Proposed Rulemaking

FDA and manufacturers didn't give up until late 1999, after the ISO and hospital industry squared off with them.



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NEW HABIT TO FORM if you want to move into the medical device and software space:

- Every time you meet with your team, allow 10 minutes at the end to discuss these two issues:
 - What else can we or should we do to MAKE SURE that
 - a) no patient is hurt or killed by our actions, and
 - b) we can prove that with documentation if necessary.

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<p>Medical Devices are a serious business! (They're not magic, but, yes, there are real dangers.)</p> <p>I investigated my first device-induced patient death for ECRI in 1976, but in this 1993 incident, one of MY ventilators was in the room where the "explosion" occurred.</p> <p>Good thing I had the documentation to prove to the FDA, ECRI, and the hospital that we did our job right!</p>	<p><small>Hospital Explosion Claims Three Lives By CRAIG WOLFF New York Times (1857-Current File): Sep 2, 1993; ProQuest Historical Newspapers The New York Times Pg. A1</small></p> <p><i>Hospital Explosion Claims Three Lives</i></p> <p>Three people were killed when a respirator supplying oxygen to an elderly woman exploded at Maimonides Medical Center in Borough Park, Brooklyn, the Fire Department said.</p> <p>Hospital engineers had worked on the machine several hours before the explosion, after nurses and other workers complained that it was giving electrical shocks, a fire official said.</p> <p>Hospital officials said they had no knowledge that the machine had been under repair and no indication that it had malfunctioned. But fire officials said they had taken sworn statements from hospital employees.</p> <p>The blast, at 5:42 A.M. in the private, nonprofit hospital, set off a fearful evacuation, as hospital workers, using sheets as stretchers, frantically dragged patients through smoky corridors and then carried them down six flights of stairs.</p> <p>Fire officials later praised nurses and other hospital staff members for containing the fire and removing more than 120 patients.</p> <p><i>Article, page B1.</i></p>
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Sum it up: Servicer and Servicer Partnership Opportunities...

1. Create joint CE and IT service teams that are fully aware of – and able to properly support – the appropriate technical standards.
2. Learn how to support IHE-compliant medical devices, because their plug-and-play characteristics will end proprietary dead-ends.
 - Those will be emerging in 2006-2008.
3. Develop and enforce verification testing AND DOCUMENTATION after repairs, reconfiguration, and upgrades.
 - Don't let you or your partnership be torpedoed by regulatory or legal intervention.

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Healthcare IT Investments What we've covered?

- Characteristics of today's market?
- Trends for the future market?
- What is driving the changes?
- What is facilitating the changes?
- Critical success factors for servicers and service partnerships:
 - Successful seamless, reliable, customer-centric services
 - Aware, competent management of the risks and regulatory challenges

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Information Sources

- www.ACCEnet.org and www.ACCEnet.org/IHE
- www.HIMSS.org/IHE
- www.RSNA.org/IHE
- www.ACC.org/IHE
- www.IEEE1073.org

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**Grab a
seat; the
fun's just
beginning!**



**Thank you for your
attention and participation!**

Please join me in solving these challenges!

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